



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

FEB 23 1999

The Honorable Jay Dickey  
U.S. House of Representatives  
2453 Rayburn House Office Building  
Washington, DC 20515

Dear Mr. Dickey:

Thank you for your letter dated February 11, 1999, concerning the recent announcement by the Director of the National Institutes of Health (NIH) regarding federal funding for research utilizing human pluripotent stem cells. As you know, this research has the potential to lead to great progress in our treatment of debilitating and deadly diseases, our understanding of human development and our ability to develop and test new drugs. Stem cell research is richly promising, yet raises important ethical issues. Therefore, Dr. Varmus and his colleagues at the National Institutes of Health (NIH) will proceed with great caution to ensure that the highest standards are set before moving forward in this area.

In keeping with the important ethical concerns that must be considered, the NIH plans to proceed in a careful and deliberate fashion to develop rigorous guidelines. A working group of the Advisory Committee to the Director of NIH will develop guidelines for the conduct of research using pluripotent stem cells and will recommend an oversight mechanism for protocol review. The National Bioethics Advisory Commission is studying these issues and will provide us with advice that -- together with counsel from outside experts, Congress and other interested parties -- will help ensure appropriate oversight.

First and foremost, these guidelines will ensure that any research funded in this area is consistent with the prohibition on federal funding for human embryo research contained in section 511 of the HHS appropriations law. Since this prohibition was first enacted in 1996, the Department of Health and Human Services (HHS) has conscientiously adhered to its strictures. For example, we have included the restriction on the use of funds in the NIH Grants Policy Statement and have issued notices reminding NIH intramural staff and the extramural research community that they must observe the prohibition. When necessary, we have not and will not hesitate to take appropriate enforcement action. I am firmly committed to our continued adherence to the law.

Your letter makes specific inquiries regarding a legal memorandum on this subject from the HHS General Counsel. You suggest that the legal analysis is problematic because it relies on a new definition of human embryo that would undermine the Congressional prohibition. In fact, the memorandum relies on the definition provided in the statute itself. The statute defines human embryo as "any organism ... that is derived ... from one or more human gametes or diploid cells."

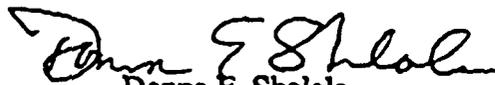
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The legal memorandum, relying on the scientific definition of the word "organism", concludes that the stem cells at issue are not organisms and therefore cannot be considered human embryos under section 511 of the HHS appropriations law.

The prohibition on federal funding for human embryo research bars the expenditure of federal funds for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded or knowingly subject to greater than minimal risk. You suggest that this provision should be read to also bar federal funding for research which follows or depends upon the destruction of or injury to a human embryo. The plain language of the statute supports the opinion issued by the General Counsel. The law applies by its terms to research in which "a human embryo or embryos are destroyed, discarded" or subjected to more than minimal risk, and not to research preceding or following such research projects. Moreover, I have been advised that there is nothing in the legislative history to suggest that the provision was intended to prohibit funding for research in which embryos -- organisms -- are not involved.

I have reviewed our Department's position and am reassured that proceeding cautiously with research on existing pluripotent stem cell lines is both legal and appropriate. Further, it will allow the NIH to foster world-class research on stem cells, assure appropriate oversight, and bring together the finest minds and facilities to further medical and scientific advances. Allow me to assure you that the NIH understands and respects the deep convictions of people in the research, academic and religious communities, and in Congress, and intends to seek the advice and comment of those communities as we move ahead. I look forward to working with you to ensure that the legal and ethical issues involved in this extremely promising area of research are addressed.

Sincerely,

  
Donna E. Shalala